REMARKS

Claims 1-2, 4-18, 20-23, 25, 27-37, 39, and 41 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

Amendments to the Claims

Applicants amend claims 30-33 to depend from claim 1. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

The Examiner rejects claims 30-33 pursuant to pursuant to 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 30-33 are amended as suggested by the Examiner, thereby obviating the basis for the Examiner's rejection.

Rejections Pursuant to 35 U.S.C. §103

Malaviya

The Examiner rejects claims 1, 2, 4-18, and 30-33 pursuant to 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Publication No. 2003/0036797 of Malaviya et al. ("Malaviya"). Applicants respectfully disagree.

Claim 1 recites that the cell growth conduit flap contacts a tibial surface, extends to the synovium, and communicates biological materials to a tissue defect in the meniscus. Claim 1 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Applicants submit that claim 1 distinguishes over and is not obvious in light of Malaviya and represents allowable subject matter.

1. Malaviya does not teach or suggest the claimed density range for cell growth conduit flap.

Malaviya fails to teach or even suggest a cell growth conduit flap with a density in the range of about 150 mg/cc to 350 mg/cc. The Examiner admits that "Malaviya does not specifically disclose that the density of the covers is in the range of about 150 mg/cc to 350 mg/cc." However, the Examiner argues that Malaviya discloses that "the covers may have a

density in the range of 872-933 mg/cc and that the properties of the covers may be varied depending on the process conditions to yield a density of 4-994 mg/cc (par.142)." The Examiner then argues that "it would have been obvious to modify the density of the flap since Malaviya does disclose methods of generating different densities as well as various values for densities." The Examiner is incorrect and continues to misrepresent the disclosure of Malaviya.

Malaviya discloses that the covers are formed from sheets of layered ECM, such as SIS. *See* Malaviya at paragraph 0140. Malaviya also discloses that the layered ECM can be processed to form "a toughened SIS laminate formed from twenty (20) layers of SIS material compressed in a vacuum bed at a temperature of 30° C. for 1 hour." Malaviya at paragraph 0142. This material was "determined to have a density of about 0.933+/-0.061 g/cm^3." *Id.*. Malaviya also discloses that "the density and other properties of such toughened ECM laminates can be varied with variations in processing conditions." Malaviya provides context for the material properties of the toughened laminate, comparing it to a commercially available product with a density of 0.466+/-0.074 gm/cm^3 and another "hardened SIS device" that "can be made with a density of 0.747+/-0.059 gm/cm^3. *Id.* Malaviya also discloses an "SIS foam" that can have "a substantially lower density of 0.091+/-0.019 gm/cm^3; 0.035+/-0.012 gm/cm^3; or 0.006+/-0.002 gm/cm^3." There is, however, no teaching or suggestion that the SIS foam is in any way related to the layered ECM materials that Malaviya teaches form the covers or even that it could be used as a cover material. Indeed, the covers are specifically disclosed as being formed of layered ECM, not an SIS foam.

Malaviya thus merely discloses several layered ECM materials with densities significantly higher than Applicants' claimed range and a single SIS foam material with a density significantly below the claimed range. There is no teaching or suggestion in Malaviya that, as alleged by the Examiner, the properties of the layered ECM covers could be varied to yield a density range including the density of SIS foam. Indeed, there is no teaching or suggestion of any material with a density within Applicants' claimed range, and likewise no teaching or suggestion that the densities disclosed by Malaviya form part of any continuous range of possible densities. To the contrary, the densities disclosed by Malaviya are isolated values – one related to SIS foam and three related to layered ECM. Malaviya's discussion of these materials therefore suggests that the density of the layered ECM covers would be higher than that of the commercially available product, i.e., greater than 0.466+/-0.074 gm/cm^3 and also that any variation in cover density would be in a range greater than 0.466 gm/cm^3. The Examiner's assertion that Malaviya discloses that it would have been obvious to modify the density of the flap over a range of

densities including densities as low as the density of an SIS foam therefore lacks any basis in the teachings of Malaviya.

2. Malaviya does not teach or suggest a cell growth conduit flap that extends to the synovium.

Furthermore, Malaviya fails to teach or suggest a cell growth conduit flap that contacts a tibial surface, extends to the synovium, and communicates biological materials to a tissue defect in the meniscus. The Examiner continues to argue that "the device of Malaviya is capable of contacting the tibial surface and extending to the synovium." This is incorrect. According to the teachings of Malaviya, the covers 232, 234, which the Examiner argues form the claimed cell growth conduit flap, cannot extend to the synovium. Malaviya teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to extend to the synovium. Therefore, according to the teachings of Malaviya, the cell growth conduit flap would not be capable of extending to the synovium.

Moreover, even if the device could be positioned such that the covers 232, 234 extended to the synovium, in such a position the device would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device," as taught by Malaviya. *See* Malaviya at Par. 0018. The Examiner now argues that "if the device of Malaviya were extended to the synovium, it could still be in contact with the side portions of the surrounding tissue of the remaining meniscus such that it does not go against the teachings of Malaviya." The Examiner is incorrect. As previously discussed, Malaviya teaches that the outer portion of the meniscus is retained. In particular, Malaviya specifically teaches that the device is positioned "against the rim 18 left by the surgeon." Malaviya at paragraph 0140. The "surrounding tissue" that Malaviya teaches would be in contact with the device is not merely the "side portions of the surrounding tissue," as alleged by the Examiner. Instead, the "surrounding tissue" must include the rim 18, i.e., the retained radially outer portion of the original meniscus. Therefore, positioning the device of Malaviya such that the covers extended to the synovium would run contrary to the teachings of Malaviya. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the

claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

3. Malaviya does not teach or suggest a cell growth conduit flap that communicates biological materials to a tissue defect in the meniscus.

The Examiner now also argues that "Malaviya distinctly shows portions of the cover including the tabs shown in fig.41 that extend beyond the meniscus to the synovium. As these tabs are an extension of the flap, and are formed of the same material, they are capable of communicating biological materials to the tissue defect." The Examiner is incorrect. Malaviya teaches only that the tabs are fastened to surrounding tissue. *See* Malaviya at paragraphs 0169-0170. There is no teaching or suggestion in Malaviya that the tabs communicate biological materials to a tissue defect in the meniscus, much less that cells and nutrients travel through the tabs themselves. Malaviya merely teaches that blood flow is channeled by the device. *See* Malaviya at paragraph 0024. Malaviya later clarifies that that fluids will "infiltrate open space" between the upper and lower covers. Malaviya at paragraph 0153.

In contrast, Applicants' invention provides a cell growth conduit flap with material properties and a structure that communicate biological materials to a tissue defect in the meniscus. *See, e.g.*, published application at paragraph 0033. Malaviya teaches that fluids are simply channeled through the open space between layers of the device and thus fails to teach a cell growth conduit flap that communicates biological materials.

Discussion

In light of the deficiencies of Malaviya, the claimed invention would not have been obvious to one of ordinary skill in the art relying on Malaviya. As discussed above, Malaviya fails to teach or suggest (i) covers of the claimed density range, (ii) a cell growth conduit flap that extends to the synovium or (iii) a cell growth conduit that communicates biological materials to a tissue defect in the meniscus. In particular, it would not have been merely routine experimentation for one of ordinary skill in the art to optimize the density of Malaviya's cover materials to achieve the claimed invention, as alleged by the Examiener.

The Examiner relies on *In re Aller, 220 F.2d 454 (CCPA 1955)* ("*In re Aller*") to remedy the deficiencies of Malaviya with respect to the claimed density range, contending that under *In re Aller*, the claimed range would have been obvious at the time of Applicants' invention since "it

is not inventive to discover the optimum or workable ranges by routine optimization." Applicants respectfully submit that *In re Aller* is not applicable here. First, as discussed above, Malaviya fails to disclose any density within or including the claimed range. Malaviya thus fails to disclose even the general conditions of the claim, as required under *In re Aller*. Second, the M.P.E.P. and well established case law specifically provide that a particular parameter must already be recognized as a "result-effective" variable - that is, a variable which achieves a recognized result - before "optimum or workable ranges" of a variable can be characterized as "routine experimentation." By failing to teach or suggest a cell growth conduit flap that communicates biological materials, Malaviya also fails to recognize the desired result. Malaviya therefore fails to provide any teaching or suggestion to one of ordinary skill in the art regarding optimum or workable densities for communication of biological materials using such a flap. It would therefore not have been obvious to one having ordinary skill in the art to optimize the density of Malaviya's covers for use as a cell growth conduit flap.

Accordingly, independent claim 1 distinguishes over Malaviya and represents allowable subject matter. Claims 2, 4-18, and 30-33 likewise distinguish over Malaviya by virtue of their dependence on claim 1.

Malaviya in view of Vallee

The Examiner rejects claims 21, 25, and 27 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of US Patent No. 4,952,404 of Vallee at al. ("Vallee"). Applicants respectfully disagree.

Claim 21 recites positioning the tissue repair scaffold in contact with a defect in a meniscus while positioning the cell growth conduit flap in contact with a tibial surface and the synovium. The Examiner admits that "Malaviya does not specifically disclose the step of positioning a cell growth conduit flap in contact with the synovium." The Examiner thus relies on Vallee to remedy the deficiencies of Malaviya. In this regard, the Examiner asserts that Vallee "teaches that it is known that meniscal tears may be healed if they communicate with the synovial membrane." The Examiner then argues that it would have been obvious to one of ordinary skill in the art at the time of the invention to "modify the placement of Malaviya such that the covers contact the more vascularized synovium in order to promote healing of the meniscus as taught by Vallee."

At the outset, Vallee merely discloses that "meniscus can be healed by connective tissue provided that the tear communicates with the synovial membrane laterally." Vallee at col. 1, lines 17-19. There is no teaching or suggestion in Vallee regarding the placement of an implant. Moreover, the covers 232, 234 of Malaviya, which the Examiner argues form the claimed cell growth conduit flap, cannot be positioned in contact with a tibial surface and the synovium without disregarding the express teachings of Malaviya. As discussed in more detail above, Malaviya teaches that the "adjacent radially outer portion of the original meniscus" is retained and contacts the device. The retained radially outer portion of the original meniscus thus prevents the device from being positioned in a manner that would allow the covers 232, 234 to contact the synovium. Moreover, even if the device could be positioned such that the covers 232, 234 contact the synovium, in such a position the device would no longer "conform to the space into which it is inserted such that the surrounding tissue of the remaining meniscus is in contact with the device," as taught by Malaviya. *See* Malaviya at paragraph 0018. Therefore, according to the teachings of Malaviya, the cell growth conduit flap would not be capable of extending to the synovium. The modification proposed by the Examiner would therefore change the principle of operation of Malaviya. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. MPEP 2143.01(VI); *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The Examiner therefore fails to present a prima facie case of obviousness with respect to claim 21.

Furthermore, claim 21 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Malaviya fails to teach or even suggest a cell growth conduit flap with a density in the range of about 150 mg/cc to 350 mg/cc for at least the reasons discussed above with respect to claim 1. Accordingly, claim 21, as well as claims 22-23 and 39, which depend therefrom, distinguish over Malaviya in view of Vallee and represent allowable subject matter.

Claim 25 recites positioning the cell growth conduit flap in contact with a tissue defect in a meniscus and in contact with a tibial surface and the synovium. Claim 25 also recites that the density of the cell growth conduit flap is in the range of about 150 mg/cc to 350 mg/cc. Applicants' arguments with respect to claim 21, above, apply with equal force to claim 25. Accordingly, claim 25, as well as claims 27-29 and 41, which depend therefrom, distinguish over Malaviya in view of Vallee and represent allowable subject matter.

Malaviya in view of Vallee and Li

The Examiner rejects claims 22, 23, 28, and 29 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of Vallee and further in view of US Patent No. 4,790,819 of Li et al. ("Li"). Applicants respectfully disagree.

First, Li fails to remedy the deficiencies of Malaviya in view of Vallee. Claims 22-23 and claims 28-29 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya in view of Vallee for all the reasons discussed above with respect to claims 21 and 25. The Examiner admits that Malaviya does not disclose the rasping step recited in claims 22 and 23. The Examiner relies on Li to teach the rasping step. Although Li teaches "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium," Li does not remedy the deficiencies of Malaviya in view of Vallee with respect to the features recited in claim 21 and 25 from which claims 22-23 and 28-29 depend. *See* Li at col. 1, lines 27-31.

Second, contrary to the Examiner's assertions, Li does not disclose rasping the meniscus in combination with placement of a fibrin clot material. Li discloses "a delivery device for depositing an exogenous fibrin clot into a wound site during an arthroscopic surgical operation." Li at Abstract. As discussed above, claims 21 and 25, as amended, recite positioning the cell growth conduit flap in contact with the synovium. In the background of the invention, Li discloses "using an arthroscopy rasp to abrade the superior and inferior parameniscal synovium to increase blood supply to the meniscal tear." (Li at Col. 1, lines 27-31). However, Li does not teach or suggest depositing the fibrin clot material in contact with the synovium. Li merely discloses injecting "a quantity of fibrin clot material into the meniscle tear within the wound site." (Li at Col. 6, lines 63-65). In addition, Li does not disclose using the rasping step in combination with depositing the fibrin clot material. Indeed, Li's invention represents an improvement to methods that require rasping the synovium to create a fibrin clot.

Regardless, Li fails to remedy the deficiencies of Malaviya in view of Vallee because Li fails to teach or suggest that the fibrin clot material is placed in contact with the synovium or a cell growth conduit flap with a density in the claimed range. Claims 22, 23, 28, and 29 therefore distinguish over Malaviya in view of Vallee and Li and represent allowable subject matter.

Malaviya in view of Schwartz

The Examiner rejects claims 20 and 34-37 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of US Patent No. 6,468,314 of Schwartz et al. ("Schwartz"). Applicants respectfully disagree.

At the outset, claims 20 and 34-37 ultimately depend from claim 1 and therefore distinguishes over Malaviya for all the reasons discussed above with respect to claim 1. Schwartz fails to remedy the deficiencies of Malaviya with respect to the claimed density of the cell growth conduit flap.

Moreover, one of ordinary skill in the art would not have modified the covers 232, 234 of Malaviya, which the Examiner argues form the claimed cell growth conduit flap based on the void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. Thus, even if it would have been obvious to modify Malaviya in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 20 and claims 34-37 distinguish over Malaviya in view of Schwartz and represents allowable subject matter.

Malaviya in view of Vallee and Schwartz

The Examiner rejects claims 39 and 41 pursuant to 35 U.S.C. §103(a) as being unpatentable over Malaviya in view of Vallee and further in view of Schwartz. Applicants respectfully disagree.

Claims 39 and 41 depend from claims 21 and 25, respectively, and therefore distinguish over Malaviya in view of Vallee for all the reasons discussed above with respect to claims 21 and 25.

Moreover, claims 39 and 41 each recite that the cell growth conduit flap has a void volume in the range of about 50% to 95%. However, as discussed above with respect to claim 20, one of ordinary skill in the art would not have modified the covers of Malaviya based on the

void volume of the insert 16 disclosed by Schwartz. The insert 16 is contained within a porous film 22 formed of bio-absorbable material. Schwartz at col. 9, lines 34-36. Thus, even if it would have been obvious to modify Malaviya in view of Schwartz, presumably one of ordinary skill in the art relying on Schwartz would have modified the mass of biological material 60 contained within the covers, not the covers themselves, to have the at least 95% voids by volume taught by Schwartz. Such a modification would clearly fail to teach or suggest the claimed void volume range of a cell growth conduit flap.

Accordingly, claims 39 and 41 distinguish over Malaviya '797 in view of Vallee and Schwartz and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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